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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/585,821	06/01/2000	Yuan-Di Chang Halvorsen	5750-8B	4699
28977	7590	02/12/2004	EXAMINER	
MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921			SAUCIER, SANDRA E	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 02/12/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/585,821	<b>Applicant(s)</b> HALVORSEN ET AL.	
	<b>Examiner</b> Sandra Saucier	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

DETAILED ACTION

Claims 16–31 are pending and are under examination.

Claim Rejections – 35 USC § 112  
NEW MATTER

Claims 16–31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claimed method is broader than the method originally claimed or disclosed in the body of the specification or in the original claims.

The method taught on page 16 of the specification requires fractionation of the conditioned media of adipocytes differentiated from preadipocytes BY THE METHOD OF THE INVENTION, which is the method presented on page 9 to differentiate preadipocytes to adipocytes. This is a much narrower generic description than the instantly claimed invention. Further, original claim 6 also requires many more steps than instantly presented in the newly broadened claims. The instant claims lack support as they are a broadening of the original specification. One is not free to broaden the claimed invention by deleting steps disclosed in the generic disclosure of the specification and original claims after time of filing. The broadest disclosure should be made in the specification as filed and not attempted to be made in claims filed far after the filing date of the original disclosure.

Step c also lacks support in that it appears to be broader than example 3 which is cited as the support for this recitation. Example 3 has a specific procedure for comparing the pattern, which is not included in the newly claimed method. The generic description at page 16 states that the method comprises “fractionating the conditioned medium of the differentiated adipocytes”. No generic disclosure of “comparing” is seen.

Further, there is limited support for the term “genetically modified” in claim 31. The specification states that the cells may be transfected with exogenous DNA. This is a much narrower term than the phrase “genetically modified” which is not restricted to transfection as disclosed.

One is not free to deconstruct and reconstruct a claimed invention after time of filing. The generic description or an original claim should contain the broadest concept of the invention, not newly created claims filed in a continuation or divisional application. This is new matter because it introduces a new, broader concept which was not the concept originally disclosed as evidenced by the generic disclosure and the original claims. New matter does not only include the insertion of new material but the introduction of new concepts such as the broadening of the original disclosure.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification. Please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but relying on specific examples to provide support for a generic concept.

### Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16–31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilberfarb *et al.* [U11] or US 6,071,747 [A] in view of the Gibco Catalog [U].

The claims are directed to a method of identifying proteins or peptides secreted from a human adipocyte comprising:  
isolating human preadipocytes,  
differentiating the preadipocytes with a medium comprising a defined medium, 1–4.5g/l glucose, cAMP inducer, glucocorticoid/analogue, insulin/analogue, PPAR $\delta$  agonist/RXR agonist,  
comparing the pattern of protein/peptide secreted by the preadipocytes vs. the adipocytes,  
identifying the proteins/peptides secreted by the adipocytes.

Zilberfarb *et al.* disclose a method of isolating a protein, leptin, from preadipocytes which have been differentiated into adipocytes by use of an differentiation medium comprising DMEM/F12, cAMP inducer, glucocorticoid/analogue, insulin/analogue, PPAR $\delta$  agonist/RXR agonist, identifying a protein, such as leptin, secreted by the PAZ6 (preadipocytes) once they have been differentiated. Please note that DMEM/F12 contains 3.15g/l glucose (Gibco Catalog).

US 6,071,747 disclose a method of studying proteins expressed by adipocytes differentiated from preadipocytes (col. 4, l. 22) by use of a differentiation medium, generically described in col. 3, l. 57 as containing insulin, and specifically in Example 1 having a base of DMEM/F12 biotin, pantothenate, FBS, dexamethasone, pioglitazone, IBMX and other components.

The primary references lack the specific disclosure of comparing the pattern of proteins secreted by the differentiated cell vs. the preadipocyte.

The step of comparing the pattern of proteins secreted by the differentiated adipocytes to the pattern of proteins secreted by the preadipocytes would have been obvious because Zilberfarb *et al.* on page 806

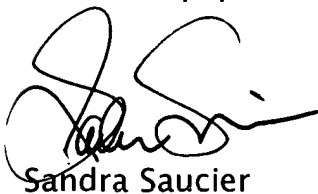
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discloses that PAZ-6 cells produce leptin once they have been converted into adipocytes. This means that at least the presence of leptin which is secreted into the medium has been compared between the preadipocyte and the adipocyte medium. Further, US 6,071,747 discloses that the PAZ6 cells and their differentiation may be a model for studying proteins expressed by the adipocytes (col. 4, l. 22). Comparing the pattern of proteins before and after an event is a routine method of determining changes in protein expression.

One of ordinary skill in the art would have been motivated at the time of invention to compare protein patterns in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197. The number of the Fax Center for the faxing of official papers is (703) 872-9306.

A handwritten signature in black ink, appearing to read 'S. Saucier', is written over the printed name 'Sandra Saucier'.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
February 5, 2004